UNITED STATES DISTRICT COURT
SOUTHER DISTRICT OF NEW YORK

ANTHONY M. SOKOL, Plaintiff, v. **WYETH, INC.,** and **WYETH PHARMACEUTICALS, INC.** Defendants	Civil No. 1:07-cv-08442-SHS **COMPLAINT** **JURY DEMAND**

I. INTRODUCTION

1. Plaintiff, Anthony M. Sokol, files this Complaint of Discrimination against his former employer, Wyeth, Inc. and Wyeth Pharmaceuticals, Inc. pursuant to the employee protection provisions of the Sarbanes Oxley Act, 18 USC §1514A, and the Americans with Disabilities Act, 42 U.S.C. § 12117(a). This complaint alleges that Plaintiff was discriminated against by the termination of his employment on September 23, 2005, and by suspension of him from said employment on August 30 and September 19, 2006 prior to said termination.

2. Plaintiff's primary employment responsibility throughout his employment was to perform the functions of a manufacturing scientist in the production of the Prevnar vaccine. Although Plaintiff had since his employment began in 2003 been proactive in identifying quality and safety issues in the manufacture of the Prevnar vaccine, he became especially concerned and vocal regarding these issues in early 2005. By the summer of 2005, he was experiencing harassment and intimidation from his supervisory chain as a result of advocating resolution to the quality and safety concerns and issues he was raising. In furtherance of Plaintiff's efforts to seek

resolution of his more serious concerns and to lessen the hostile work environment that was being created for him, he filed internal complaints on August 23 and 30, 2005 with the employer's Ethics and Compliance Offices. In these complaints, he listed specific quality and safety issues that needed immediate attention if the employer was committed to protecting the infant consumers of the vaccine and company shareholders. Plaintiff specifically raised concerns that the Defendants were misrepresenting and concealing data from the federal Food and Drug Administration (FDA) and that the FDA should be notified. Plaintiff also specifically raised concerns that the company was involved in fraudulent practices, and was failing to make all legally required disclosures of material information to shareholders.

3. Shortly after filing the August 23, 2005 internal complaint with the company's offices and management in New Jersey and New York, Plaintiff was suspended from employment and ordered to undergo a behavioral examination by company doctors. Both company doctors and his own physician certified his fitness for work. Upon return, the Plaintiff filed a supplemental complaint with the Ethics and Compliance offices on August 30, 2005. Shortly thereafter he was again suspended and escorted from the work site. On September 23, 2005, he was terminated in writing, again for unstated reasons. Despite Wyeth having a stated disciplinary procedure and performance improvement procedure, neither were followed and/or communicated to Plaintiff.

II. PARTIES

4. The Plaintiff is a resident of Pennsylvania and a citizen of the United States. From March 3, 2003, until September 23, 2005, Plaintiff was employed as a Manufacturing Scientist with Wyeth, Inc. and Wyeth Pharmaceuticals, Inc., a subsidiary and "reporting segment" of

Wyeth, Inc. under the rules of the Securities and Exchange Commission, operating at Pearl River, New York.

5. The Defendants are Wyeth, Inc. and Wyeth Pharmaceuticals, Inc., both Delaware corporations. Wyeth, Inc. and Wyeth Pharmaceuticals, Inc. maintain their executive offices at Five Giralda Farms, Madison, NJ 09940. Both corporations are referred to hereafter in the singular as WYETH or "Defendant". Wyeth is a publicly traded corporation.

III. JURISDICTION

6. Jurisdiction of this action is established under 28 U.S.C. § 1331 on the basis that this complaint presents federal questions under the Sarbanes Oxley Act, 18 USC section 1514A, and the Americans with Disabilities Act, 42 U.S.C. § 12117(a).

7. Plaintiff administratively exhausted his claim under the Sarbanes Oxley Act in the United States Department of Labor, Case No. 2005-SOX-107, and said claim was dismissed following the giving of notices to the Department of Labor under 29 CFR Part 1980.114(a) and (b) of his intent to remove his claim to this court, thereby conferring de novo jurisdiction on this court pursuant to 18 U.S.C. § 1514A(b)(1)(B). As to his discrimination claims under the Americans with Disability Act, the Plaintiff exhausted his remedies with, and has received a right to sue letter from, the Equal Employment Opportunity Commission. This court has jurisdiction over his Americans with Disabilities Act claims under 42 U.S.C. §§ 2000e-5(f).

IV. VENUE

8. Venue lies in this United States District Court under 28 U.S.C. § 1991(b) and (c) by virtue of the fact that the defendants have offices in and/or operate in this judicial district, and

the conduct complained of herein occurred and/or resulted in injury to the plaintiff in this judicial district.

V. BACKGROUND FACTS

A. Prevnar Vaccine Production and WYETH Profitability:

9. In 1999, WYETH began pre-production of Prevnar, a new biological vaccine for infants. Prevnar is part of a family of conjugated vaccine products that is manufactured in a complex and potentially dangerous process involving 12 months of detailed manufacturing and quality assurance activity prior to release and distribution. The product is manufactured at WYETH'S Sanford, NC and Pearl River, NY sites. The vaccination introduces and then kills live bacteria and thereby "teaches" the immune system of two to twelve month old infants to recognize and protect themselves from several life-threatening diseases (e.g., pneumonia, middle ear infection, meningitis).

10. In February 2000, the Center for Biological Evaluation and Research, a division of the U.S. Food and Drug Administration (FDA), licensed WYETH to begin distribution of Prevnar based upon testing, licensing and certification documentation submitted with WYETH'S FDA applications. These documents certified that all testing results and data were true and correct and certified that manufacturing operations would be conducted in compliance with cGMPs ("Current Good Manufacturing Practices"). Current Good Manufacturing Practices are regulatory requirements for all manufacturers of pharmaceutical and biological vaccine products and are codified by the FDA at 21 C.F.R., Parts 210, 211, and 600.

11. Prevnar is one of several early childhood vaccines recommended for every newborn infant by some physician organizations and the Center for Disease Control. However, a

growing number of medical professionals have begun to question the cost benefit and safety of large and indiscriminate Prevnar use. In October 2000, the Advisory Committee on Immunization Practice (ACIP) approved use of Prevnar in vaccination of all 2, 4, 6, and 12 month olds in the United States. Approximately forty percent of Prevnar doses are purchased by the U.S. Government and distributed through the Vaccines for Children Program.

12. It is this universal feature of Prevnar distribution that has accounted for the rapid billion dollar growth in Prevnar sales, which in turn are based on WYETH's claims of the vaccine's consistent production methods and non-variable quality control and procedures. In the event that these assurances were found to be unreliable, pediatricians would reduce prescriptions of the vaccine to a more "at risk" infant population. Prevnar sales and profits could dramatically decline if universal distribution were replaced by patient-specific prescription. Share value would be materially and adversely affected.

13. Manufacturing and distribution of Prevnar grew rapidly following the February 2000 FDA approval as well as its October 2000 approval by the ACIP. Prevnar sales in 2004 exceeded $1 billion. Public financial reports filed with the U.S. Securities and Exchange Commission (SEC) indicate Prevnar has been one of the key contributors to growth in operating cash flow and net income of WYETH since 2002. Prevnar sales and cash flow are a major factor in the price of WYETH stock.

B. The Federal Court Consent Decree Regarding Adulteration:

14. On October 3, 2000, WYETH entered into a Consent Decree with the FDA in the United States District Court for the Middle District of Tennessee following FDA seizure of certain of the company's non-Prevnar products alleged to be "adulterated", within the meaning of

21 U.S.C. § 351(a)(2)(B). Adulteration denotes any product manufactured in violation of FDA rules or cGMPs, irrespective of actual "contamination" by foreign substances or organisms. Either adulteration of contamination renders a product and the entire batch or "production run" from which it was produced unlawful to sell. These seizures were based on FDA inspection reports identifying repetitive GMP manufacturing and quality assurance violations at WYETH'S manufacturing sites in Marietta, PA and Pearl River, NY. FDA allegations that products were not being manufactured in accordance with GMPs led to WYETH's non-admission of wrongdoing and agreement to pay $30 million as disgorgement of profits in connection with these violations. The consent decree further placed *all* WYETH operations and products produced in whole or in part at Pearl River, NY under continuing FDA oversight for a minimum period of five years. Any cGMP violations, adulteration or contamination of Prevnar at Pearl River would be subject to consent decree enforcement and sanctions in addition to the normal regulatory regime. Any consent decree enforcement action, or even notice thereof, would require WYETH to disclose it in multiple SEC reports.

C. Specific Concerns in Prevnar® Production, Quality Control and Reporting

15. As described in factual detail in his internal complaint dated August 23, 2005 (Attachment A hereto) and reiterated in supplemental internal complaint dated August 30, 2005, Plaintiff raised the specific concerns in the following subject areas with Defendant's managers:

(1) Problems in Prevnar® Polysaccharide Fermentation Process;

(2) Failure to Properly Address Bio-burden and Biphasic Growth;

(3) Problems with Cellular Debris;

(4) Vulnerabilities in Freezer Storage;

(5) Filter Obstructions in Prevnar Polysaccharide Purification Process; and

(6) Inadequate Manufacturing Investigation Reports (MIRS).

16. Plaintiff believed that WYETH did not self-report the above incidents to the FDA. Regardless of actual contamination, the processes that result in these anomalies evidence serious cGMP non-compliances, and constitute adulteration. Each incident represented a breakdown in WYETH'S MIR process and violated the October 3, 2000 federal court consent decree requirements. Such MIR and cGMP or consent decree failures represent material risks to shareholders and should have been disclosed.

VI. PROTECTED ACTIVITY

17. The safety and quality concerns Plaintiff raised, as set forth above, were all material issues impacting the safety and viability of the Prevnar product, and implicated risk to profitability, supply, and share values. The raising of these issues in the workplace and to managers constituted protected activity under the Sarbanes-Oxley Act.

18. On August 23, 2005, Plaintiff made the attached written report and complaint (Attachment A), which is hereby incorporated by reference, to the WYETH'S Ethics and Compliance offices in which he repeated these serious compliance issues in vaccine production above and outside of his regular chain of command. Plaintiff explained in his report that he had been raising these issues to immediate managers for at least the preceding six months but had felt compelled to press them more vigorously during the preceding 60 days. In his report, Plaintiff stated that these compliance issues involved "misrepresentations and omission about the quality of products and processes, contradictions in the statements we make to shareholders and consumers on our website and SEC filings, and failures to report or concealments from the Food

and Drug Administration (FDA)." He requested an investigation and appropriate corrective action.

19. In particular, Plaintiff's report gave as its purpose providing responsible Wyeth officials with information to assist them in investigating conduct that he reasonably believed constituted "a violation of rules or regulations of the Securities and Exchange Commission, or provision of Federal law relating to fraud against shareholders." Plaintiff specifically referenced SEC Rule 10(b), and stated that it "requires us to not make misrepresentations to shareholders, and where we have omitted to do so, to immediately provide such information as may be necessary to accurately report the conduct of our operations." Plaintiff attempted to persuade WYETH'S upper management that "without providing more accurate information and correction of past misrepresentations to the FDA, shareholders are left with the impression that we are in FDA compliance."

20. On August 30, 2005, Plaintiff submitted the attached supplemental complaint (Attachment B), which is incorporated by reference herein, to WYETH'S Ethics and Compliance offices.

21. On September 16, 2005, Plaintiff met with his immediate supervisors to discuss his concerns with quality and safety. During this discussion, Plaintiff explained his beliefs that WYETH practices, as set forth above, were harmful to consumers and shareholders, and that the FDA had a right to know about the referenced problems in Prevnar production.

VII. ADVERSE ACTIONS

22. As a result of the above stated protected activity, WYETH retaliated against the Plaintiff by taking the adverse actions listed below.

A. Hostile Work Environment Prior to Filing of Ethics Complaint:

23. On August 16, 2005, Plaintiff overheard a conversation involving WYETH managers Gregor MacMullen and Robert Repetto regarding a desire to "fire" him for not being a "team-player" and "breaking up the group." As detailed above, these managers were those to whom Plaintiff had directed most of his compliance concerns. He overheard that management had become "fed-up" with him and that they could "no longer take it."

24. Also on August 16, 2005, Robert Repetto and Gregor MacMullen addressed Plaintiff in an unprofessional and abusive tone and volume because he had asked whether or not there would still be the Tuesday morning meeting. It was at this regular meeting that Plaintiff, as a team player, tried to engage his managers and the group in discussions and resolutions of quality and safety concerns and suggestions for improvement.

25. On August 10, 2005, Dr. Williard Waterfield had become concerned with Plaintiff's conjugation experiments and his preliminary findings about polysaccharide impurity and effects. Robert Repetto appeared concerned that Plaintiff was "super-prepping" the samples. Dr. Waterfield made a demeaning and intimidating comment to him to the effect that Plaintiff must have a lot of time on his hands to perform these impurity experiments and stated that someone else was working on them.

26. On August 2, 2005, Plaintiff's volunteer efforts were labeled by Mr. MacMullen as "odd" for having helped others in the department in bringing pallets from manufacturing to prevent raw materials from getting saturated with water. Plaintiff was told that he should focus on performing only analytical tasks.

27. On July 29, 2005, Dr. Waterfield suggested that a compliance issue Plaintiff had referenced during a meeting could embarrass the company in court. This was intimidation.

28. On July 15, 2005, Mr. MacMullen sent an email to HR reporting Plaintiff as tardy and violating core values. Other employees who are not punctual were not similarly reported. This was disparate treatment.

29. On July 7, 2005, Plaintiff was shown a video by Mr. MacMullen of someone getting their head blown-off. Earlier in the year he showed Plaintiff an illustration of "how to commit suicide". This was intimidation and harassment.

30. On May 27, 2005, Plaintiff addressed the matter of core values to Mr. MacMullen and was told they are a "bunch of bullshit". Plaintiff had not observed this insulting and intimidating profanity having been addressed to other employees who had not raised safety and quality issues.

B. Hostile Work Environment After Filing of Ethics Complaint:

31. On August 23, 2005, the day after Plaintiff filed his complaint with the Ethics and Compliance offices, he was notified that his email account was temporarily suspended. Later in the day, he was informed this was just a "hoax".

32. On August 25, 2005, in a meeting with WYETH manager Williard Waterfield, Plaintiff was accused of being "threatening" in the raising of his safety and quality concerns, and admonished to perform only specifically assigned duties. He was also directed to address this manager in the future only as "Dr. Waterfield", a formality previously not demanded.

33. On August 26, 2005, Plaintiff was again cautioned to not work on matters outside of his assigned areas. It appeared that his computer access had been limited and/or that certain

files were no longer available to him. When he reported that managers appeared to be shunning him, and that he was concerned for his safety, he was told he should consult the company nurse and take time off. This urging that Plaintiff should consult the company nurse was repeated on August 30, 2005, as an email directive.

34. On September 3, 2005, a "Life Management" brochure was sent to Plaintiff at his home, which he reasonably understood to be further suggestion that he needed mental health assistance. This was harassment.

35. After meeting with the company doctor and a company nurse, and providing a letter from his own psychiatrist that he was fit for work, the Plaintiff was reinstated from his suspension on September 12, 2005. However, WYETH attempted to require him to characterize his time off during the suspension as medical leave, which he refused to do. Plaintiff asserted that this suspension constituted retaliation for his protected activity, and desired that the merits of the suspension to be included in any investigation being conducted by the Ethics and Compliance offices on his complaint and supplemental complaint.

C. Reduction in Duties and Research Opportunities:

36. WYETH maintained a policy allowing its scientists to perform discretionary research outside of regular responsibilities, so long as assigned duties were being discharged. This policy in part was to encourage scientists to discover product and process enhancements, and development of new patents. Rewards were available to scientists making valuable discoveries, which by agreement, would be WYETH'S property. In restricting Plaintiff's ability to perform discretionary research because of his complaints and disclosures about FDA and SEC violations, WYETH discriminated against him in the terms and conditions of his employment.

D. Suspension from Employment

37. On August 30, 2005, after Plaintiff requested clarification on the directive that he consult the company nurse, he was suspended from work and told not to return until further notice.

38. Within days of being cleared to return to work by the company's own medical staff, and following Plaintiff's September 16, 2005 discussion with his managers regarding his beliefs that WYETH practices were fraudulent and harmful to consumers and shareholders, and that the FDA and shareholders had a right to know about the referenced problems in Prevnar production, Plaintiff was again suspended on September 19, 2005, without reasons being given.

39. Despite Wyeth having a stated disciplinary procedure and performance improvement procedure, neither were followed and/or communicated to Plaintiff with regard to either suspension.

E. Termination from Employment:

40. On September 23, 2005, Plaintiff received a telephone call that his suspension had been made into a termination from employment. On September 26, 2005, Plaintiff received a letter of termination dated September 23, 2005. Despite Wyeth having a stated disciplinary procedure and performance improvement procedure, neither were followed and/or communicated to Plaintiff with regard to termination.

V. FIRST CLAIM FOR RELIEF: VIOLATION OF SECTION 806 OF THE SARBANES OXLEY ACT

41. Plaintiff realleges Paragraphs 1 through 40 above.

42. The complaints, disclosures, and information provided by Plaintiff to Defendant's managers regarding quality and safety problems in Prevnar production constituted protected activity under the employee protection provisions of Section 806(a)(1) and (2) of the Sarbanes-Oxley Act, 18 U.S.C. § 1514A(a)(1) and (2). Plaintiff informed the Defendant that its failure to disclose the said quality and safety problems to shareholders and the FDA was an unlawful, unethical and fraudulent violation of Rule 10(b) and other rules and regulations of the SEC.

43. Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Exchange Act Rule 10b-5 thereunder [17 C.F.R. § 240.10b-5] prohibit a company from, *inter alia*:

> employing any device, scheme or artifice to defraud; making any untrue statement of a material fact or omitting to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; or engaging in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

In failing to make the disclosures referenced above, Plaintiff reasonably believed that WYETH had violated Section 10(b) of the Act and Rule 10b of the SEC, and other rules and regulations of the SEC.

44. The above referenced documentation containing fraudulent statements and/or omissions of information, particularly BLA data, between WYETH and the FDA, was sent through the mail and/or by wire via fax and email transmission. Plaintiff reasonably believed that Defendant's use of the mails and wire facilities was a violation of one or more of the provisions of 18 U.S.C. sections 1341, 1343, 1344, or 1348 which prohibit use of the mails and wire transmission in the commission or attempted commission of any "frauds or swindles".

45. Section 906 requires that both the "chief executive officer and chief financial officer" certify with "each periodic report containing financial statements" filed with the SEC,

that the "information contained in the periodic report fairly presents, in all material respects, the *financial condition and results of operations* of the issuer." Under 17 C.F.R. § 229.303(3) and related SEC regulations, any "events", "uncertainties", or "trends" in the operations of the business which would "materially affect" income or the "relationship between costs and revenues" must be reported to the SEC, and hence, to the shareholders. In failing to disclose the contamination and adulterations referenced above, and the unexplained process variations and changes, particularly those regarding Hy-soy, Plaintiff reasonably believed that WYETH violated Section 906 and 17 C.F.R. § 229.303(3) and related SEC rules.

46. WYETH failed to conduct and/or inform the Plaintiff of its intent or efforts to conduct an investigation of his Ethics and Compliance offices complaints, particularly as to his allegations of retaliation and his requests for remediation of the same. Section 301 of the Sarbanes-Oxley Act required the Defendant, through its Audit Committee, to create a system for the early detection of fraud by establishing procedures for "(A) the receipt, retention, and treatment of complaints received by the issuer regarding accounting, internal accounting controls, or auditing matters; and (B) the confidential, anonymous submission by employees of the issuer of concerns regarding questionable accounting or auditing matters." As set forth above, Plaintiff disclosed to his management that he was being retaliated against for his protected activity under Section 806, but he had not been made aware of any effective internal procedures to allow employees to disclose internal control or audit issues as required by Section 301. Defendant had no effective procedures in place to prevent retaliation against employees who attempted to disclose misconduct, including the failure to remediate vulnerabilities with the corporation's internal controls, as required by Section 806.

47. Defendant's consideration of the Plaintiff's protected activity, as set forth above, was a contributing factor in and/or resulted in Defendant taking each of the above listed discriminatory adverse actions in violation of Section 806 of the Sarbanes-Oxley Act.

48. As a direct, proximate, and foreseeable result of Defendant's retaliation, Plaintiff has suffered loss of income, damage to his career, and severe emotional, mental, and physical distress and anxiety. He is entitled to economic and non-economic damages. Because the actions of the Defendant in violating Section 806 were aggravated and willful, Plaintiff is also entitled to punitive damages.

V. SECOND CLAIM FOR RELIEF: VIOLATION OF THE AMERICANS WITH DISABILITIES ACT

49. Plaintiff realleges Paragraphs 1 through 48 above.

50. On August 30,2005, Wyeth Nurse Shelia Burke called Plaintiff to her office, after she received complaints from Plaintiff's supervisor, to prompt him to take a medical leave of absence based upon his disability. Burke accused Plaintiff of acting aggressively toward coworkers. Plaintiff then filed and distributed a supplemental internal complaint. Burke and Plaintiff's supervisors were aware of his disability. After Plaintiff declined to take medical leave, Burke contacted Dr. Shou-Bai Chao, head of Vaccines, and Plaintiff was ordered to leave work on a medical suspension.

51. In September 2005, Plaintiff's disability was aggravated by the above listed adverse actions taken against him by the Defendant, and by the severe stress caused to the Plaintiff by his knowledge that the Defendant was manufacturing Prevnar, and infant vaccine, under quality control conditions that threatened the health and safety of children, and that

operated to perpetuate fraud upon the Defendant's shareholders. Notwithstanding his disability, Plaintiff remained able to perform her job duties.

52. Plaintiff returned to work on Monday, September 12,2005, after receiving a medical release from his personal physician and from the Defendant's company doctor. This same day Plaintiff met with Defendant's managers to review the findings of the investigation into Plaintiff's above described internal complaint. On September 19, 2005 Plaintiff was again suspended, and on September 23, 2005 was terminated on the pretext of Defendant's concerns with his disability.

53. These above referenced actions by the Defendant in suspending and terminating the Plaintiff on the pretext of concerns over his disability were in violation of her rights under the Americans with Disabilities Act, 42 U.S.C. § 12117(a).

VIII. PRAYER FOR RELIEF

54. Based on the foregoing discrimination, the Plaintiff respectfully requests he be awarded the following relief:

a. Reinstatement to the original duties and working conditions applicable at the time of his hiring, and abatement of the hostile working environment maintained against him;

b. Economic damages for lost wages and benefits, and damage to Plaintiff's career and earning capacity, in the amount of at least $500,000, or an amount to be determined at trial;

c. $1,000,000 in non-economic damages for mental and emotional distress, embarrassment and humiliation, or an amount to be determined at trial;

d. Injunctive relief requiring the Defendant to expunge all derogatory information about the Plaintiff, including records of his suspensions and termination, from Defendant's personnel records

e. Reasonable costs and attorney's fees under 18 U.S.C. § 1514A(c) and 42 U.S.C. § 12117, together with all other relief available from law and equity.

JURY DEMAND

Plaintiff requests a trial by jury of all issues.

Dated: September 28, 2007
New York, New York

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